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1.0 Policy Statement

This policy applies to designated drugs requiring prior authorization through Medicaid. Prior authorization is the mandatory advance approval by Medicaid for the use of selected high-cost, high-risk, and high-use medications. Prior authorization for designated drugs is linked to specific, pre-existing criteria for appropriate use of the medication such as diagnosis, duration of therapy, dosage, risk-benefit of treatment or other patient-specific characteristics such as prior treatment failure, etc.

2.0 Policy Guidelines

2.1 Identification of Candidate Drugs for Prior Authorization Process

2.1.1 High-Risk, High-Cost, High-Use

A drug may be considered for prior authorization if:

- The medication is being used as first line therapy where there are similarly efficacious, effective, and safe drugs available at substantially less cost.
- The drug is subject to abuse or fraudulent use.
- The medication is so costly that advance assurance of indication for use is desirable rather than retrospective analysis.
- The increase in usage of the drug is far greater than would be expected based on clinical evidence of efficacy.
- Guidelines for appropriate use are complex and/or require yearly seasonal adjustment.
- There is evidence that the medication is being used inappropriately.

2.1.2 Documentation of Baseline Use/Need in North Carolina

Drugs being considered for prior authorization are evaluated, as appropriate, by examining N.C. Medicaid recipient data relative to:

- ~~Age group, benefit groups, race/ethnicity, specialty of prescriber~~
- ~~Diagnoses of recipients~~
- ~~Length of therapy, number of prescriptions, varying dosages per patient~~
- ~~Rate of increase in use compared to~~ Annual drug costs and annual number of prescriptions for similar drugs or drug classes
- ~~Annual costs of care or costs of an episode of care~~
- Monthly tends in drug costs and number of prescriptions

The following additional data for specific drugs or drug classes may also be useful for secondary analysis of the baseline data:

- Age group, benefit groups, race/ethnicity, spescialty of prescriber
- Diagnoses of recipients
- Length of therapy, varying dosages per patient

2.1.3 Additional Questions to Consider

- Can clear criteria be written to indicate an approved use of the medication?
- Can an anticipated programmatic outcome and magnitude of desired change be identified?

- Will adding the drug to the prior authorization list place an undue hardship on one particular provider group? (This determination will be based in part on the number and type of drugs already prior authorized.)
- Have adverse health outcomes from prior authorization either (i) not been shown in previous studies or (ii) anticipated to be negligible?
- Can parameters to monitor desired outcomes and unintended consequences from prior authorization be specified?

2.2 Information Sources to Develop Criteria

DMA will develop criteria ~~will be developed~~ considering as many of the following sources as are applicable and/or available for a particular drug: ~~in order for the Pharmacy and Therapeutics Committee (Committee) of the N.C. Physicians Advisory Group (NCPAG) to understand the appropriate use of the drug and any national/local standards of care.~~

An adequate literature search including citations will consist of:

- FDA labeling
- Systemic reviews on use of the drug (e.g., AHRQ, Cochrane, NLM-indexed articles)
- Peer-reviewed literature for adequate documentation of off-label uses and nationally specified compendia for off-label use (e.g., USP DI, Micromedix, AHFS)
- Any articles on gender and/or racial differences relevant to appropriate use of the drug
- Clinical practice guidelines published by specialty societies
- Head to head studies on use of the drug compared to alternatives (drug and non-drug)

Additional sources of information:

- Medicare guidelines for use of a drug.
- Examples of criteria from other Medicaid states, ~~and~~ local health plans, and other insurers. (The intent of these benchmarks is to help evaluate the criteria in reference to populations similar to N.C. Medicaid as well as ensuring that the Medicaid population has parity with local standards of care.)
- Outcome studies related to administrative controls for a drug.
- Subspecialty and specialty input at all stages of criteria development.
- Community standards of care.

Copies of resource materials are provided to the P&T Committee at least two weeks prior to meetings. In the course of the evaluation, the Committee may need to address the issues of whether this is an appropriate candidate drug and may need to review additional information on an iterative process. It is expected that additional reference information and literature searches may be performed by the Committee based on its expert knowledge and specialty composition.

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2.3 Draft and Final Criteria

The Committee reviews the materials and drafts a recommendation to the NCPAG. The draft recommendation must include:

- Name and formulation of drug(s)
- Indications for which there is evidence to support effectivness and safety
- Criteria specific to patient subgroups (as applicable)
- List of alternative therapies that need to be tried before prior authorization can be granted (if applicable)
- ~~The drug or drugs including brand and generic names, formulation under prior authorization, and others that may not be included.~~
- ~~Specific criteria for approved use including whether a patient taking the drug before the prior authorization should be subject to the authorization. (grandfathering) and duration of the prior authorization for an individual patient~~
- ~~Clearly stated and implementable criteria (e.g., use of a specific age cut off rather than use of terms such as "old" or "young").~~
- ~~Clearly stated restrictions (e.g., criterion that does not include dosage restrictions should not be restricted on this basis).~~
- ~~Approved standard operating procedure/protocol for the pharmacy benefits manager (PBM) including referral process for appeal and any suggestions they plan to offer physicians.~~
- ~~The specific issue triggering the suggestion for prior authorization.~~
- ~~A suggested duration of prior authorization prior to monitoring programmatic and patient outcomes.~~

2.4 Ongoing Monitoring of Prior Authorization Effects

2.4.1 Utilization

Each drug that is on the prior authorization list will be ~~is~~ monitored every six months from the time of placement on prior approval to determine the effect of the prior authorization process on utilization and appropriate use. ~~The frequency of the monitoring is determined by the Committee.~~ Monitoring will include:

- Number of prescriptions
- Drug costs
- Percent finally filled
- Percent appealed
- Percent reversed
- The cost of administering the prior authorization

Information will also be collected on appeals that are based on justification that is outside of the evidence-based criteria. The Committee will monitor these data and use them to provide feedback and as educational resources for prescribers.

~~Monitoring includes usage by age, eligibility class, and diagnosis, etc. (also sex, race, and ethnicity if available) as outlined in the development of the prior authorization.~~

~~A report from the PBM of the number of approvals, denials, overrides, reasons for denial or override, and the number and nature of appeals is reviewed quarterly. Additional detail may be specified by the Committee or by the Division of Medical Assistance.~~

2.4.2 Re-review of Criteria

Each drug/drug class on PA will be reviewed for new indications and evidence-based literature at a minimum of every two years. DMA will keep records ~~are kept~~ for each prior approval as to chronological history including: date of last literature review, initiation date, date of sub-specialist review, date of NCPAG approval, date of implementation, dates of re-review and any major changes, and next date for Committee review. Minor revisions to the prior authorization list will be accomplished by the Committee and given as information to the NCPAG.

2.5 Removing a Drug from the Prior Authorization Process

If monitoring indicates that a drug should be considered for removal from the prior authorization process, the Committee assesses factors relative to utilization, cost effectiveness, efficacy, and the overall effect of removing the prior authorization requirement. The Committee makes recommendations based on findings to the NCPAG. If the drug is removed, utilization should be monitored for one year from the date the drug was removed from PA to assure the change is maintained.

~~The following examples represent reasons to consider removal of a drug from the prior authorization list:~~

A drug may be considered for removal if:

- ~~After 6 months of the prior authorization process,~~ There is no change in utilization or there is a vry low ~~and a less than 3 percent~~ denial rate; or~~. This would indicate that the use of the drug met criteria prior to prior authorization.~~
- ~~After initial desired impact of the prior authorization process, there is 6 continuous months of minimal change in utilization. This would indicate maximum effect and provider prescription change achieved. If the drug is removed, utilization should be monitored for 1 year to assure the change is maintained.~~
- Unintended negative health outcomes or negative effects on one patient group or eligibility group; or
- The cost of the prior authorization is greater than the cost savings or improvement in quality realized by its use.
- ~~There is new evidence to suggest that the conditions represented in constructing the original prior authorization have changed substantially (e.g., a new indication is approved, the cost of the drug changes, etc.).~~

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3.0 Policy Implementation/Revision Information

Original Effective Date: March 4, 2002

Revision Information:

Date	Section Revised	Change
	Section 2.1.2	The primary and secondary data that are used to evaluate drugs being considered for prior authorization was clarified
	Section 2.2	The process by which criteria are developed, the sources of information, and the role of the P&T Committee were clarified.
	Section 2.3	The content of draft recommendations from the P&T Committee to the NCPAG was modified.
	Section 2.4	This section was subdivided into two subsections addressing utilization and re-review of criteria. Section 2.4.1 describes the process for reviewing PA drugs to evaluate the effect of the PA process on utilization and appropriate use. Section 2.4.2 describes the process for review of the criteria for PA drugs.
	Section 2.5	A statement was added to indicate that drugs removed from the PA list should be monitored for one year. The criteria by which a drug may be considered for removal from the list were modified.